

Applicants : Tove Ringerike et al.  
Serial No. : 10/577,268  
Filed : April 26, 2006  
Page : 6 of 9 of Amendment in Response to March  
17, 2011 Office Action

**REMARKS**

Claims 4, 8, 9, 11-13, 15, 16, 24, and 44-52 were pending in the subject application, with claim 24 withdrawn from consideration. Applicants have herein amended claims 46 and 52 for clarity, cancelled claims 4, 9, 11-13, 15-16, 24, and 44 without disclaimer or prejudice as to Applicants' right to pursue the subject matter of these claims in the future, and added new claims 53-58.

Support for new claim 53 can be found in the specification as filed at, *inter alia*, page 7, lines 3-6.

Support for new claim 54 can be found in the specification as filed at, *inter alia*, page 7, lines 12-16.

Support for new claim 55 can be found in the specification as filed at, *inter alia*, page 7, lines 16-18.

Support for new claim 56 can be found in the specification as filed at, *inter alia*, page 7, lines 6-8.

Support for new claim 57 can be found in the specification as filed at, *inter alia*, page 7, lines 8-9.

Support for new claim 58 can be found in the specification as filed at, *inter alia*, page 7, lines 9-12.

Accordingly, this Amendment introduces no new matter and Applicants respectfully request that this Amendment be entered.

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**Claims Rejected Under 35 U.S.C. §112, Second Paragraph**

On page 3 of the March 17, 2011 Office Action, the Examiner rejected claims 4, 9, 11-13, 15-16, and 44 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out an distinctly claim the subject matter which Applicants regard as the invention.

In response, without conceding the correctness of the Examiner's position and for the purpose of expediting prosecution, Applicants have cancelled claims 4, 9, 11-13, 15-16, and 44. Accordingly, this rejection is now moot.

**Claims Rejected Under 35 U.S.C. §112, First Paragraph**

On page 4 of the March 17, 2011 Office Action, the Examiner rejected claim 52 under 35 U.S.C. § 112, first paragraph, allegedly lacking enablement for a screening assay using any test substance and any reporter gene assay to conclude that a change in the level of expression described in step (b) is accepted as a characteristic of the tested substance. The Examiner discussed the *In re Wands* factors on pages 5-7 of the March 17, 2011 Office Action and concluded that undue experimentation would be required to practice the claimed invention.

In response, without conceding the correctness of the Examiner's position and for the purpose of expediting prosecution, Applicants have amended claim 52 to more clearly recite their invention. Undue experimentation is not required to practice the invention recited by amended claim 52.

Step (b) of claim 52 has been amended to recite "a change in the level of expression of a green fluorescent protein caused by the tested substance is determined." Each of the plasmids recited by

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claim 8 encodes a green fluorescent protein, i.e., EGFP, dEGFP, or d2EGFP. Thus, each single-celled host of claim 46 has a reporter gene which encodes a green fluorescent protein.

Step (c) of claim 52 has been amended to recite "the change in the level of expression described in (b) is accepted as a characteristic of the tested substance," emphasis added. Thus, amended claim 52 does not require the determination of any previously determined "accepted characteristic" or "known property." See, March 17, 2011 Office Action, page 5. Instead, the change in the level of expression determined in step (b), regardless of magnitude, is the characteristic which is obtained by the method.

Clearly, undue experimentation is not required to practice the claimed method because measuring the expression levels of green fluorescent proteins was routine at the time of Applicants' invention. Nothing of record contradicts this.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

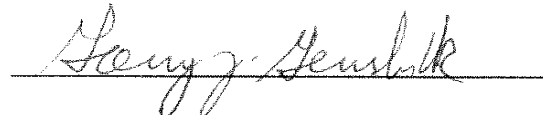
Applicants believe that the claim amendments and remarks made herein resolve all of the issues identified in the March 17, 2011 Office Action. Consequently, Applicants look forward to receiving a Notice of Allowance in connection with the subject application.

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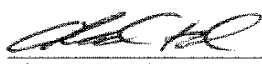
If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



Gary J. Gershik  
Registration No. 39,992  
Attorney for Applicants  
Cooper & Dunham LLP  
30 Rockefeller Plaza,  
20<sup>th</sup> Floor  
New York, New York 10112  
(212) 278-0400

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